Marked-Up Version of Amended Claims 1, 6 and 8-11

1 (Amended). A [system] cannula assembly for circulating blood in a heart comprising:

[a cannula body having a distal end for insertion through an incision]

an outer cannula including a curved portion and adapted for insertion through an incision into a heart chamber,

an inner cannula slidable within the outer cannula, the curved portion of the outer cannula directing passage of the inner cannula beyond the distal end of the outer cannula, the inner cannula having an interior lumen defining a first interior flow path to circulate blood,

the inner and outer cannulas defining between them a second interior flow path to circulate blood,

[and including first and second interior flow paths to circulate blood,

a conduit communicating with one of the first and second flow paths and being sized to extend, in use, beyond the distal end of the cannula body for passage into a heart chamber, to thereby input or outflow blood from the heart chamber, the cannula body including a first curved portion to direct passage of said conduit from the distal end into the heart chamber,] and

a port communicating with the [other one of the first and] second interior flow path[s to input or outflow blood at the distal end].

6 (Amended). An [system] assembly according to claim 1,

wherein the outer cannula has a first proximal end extending outside of the incision,

wherein the inner cannula has a second proximal end extending outside of the incision,

and

wherein the first and second proximal ends are adapted and configured for coupling to a pump

[further including a pump communicating with the proximal end of the cannula body and operating to circulate blood through the first and second interior flow paths].

8 (Amended). An assembly according to claim 1, wherein the curved portion of the outer cannula is adjacent the distal end of the outer cannula [for access to an interior body region comprising a body defining a lumen having a distal region, the lumen including a bend in

the distal region].

9 (Amended). An assembly [cannula] according to claim [8] 1, wherein the [lumen] outer cannula includes a main axis, and wherein the [bend] curved portion of the outer cannula is bent at an angle between 0 and 360 degrees relative to the main axis.

10 (Amended). An assembly [cannula] according to claim 9, wherein the angle is between 0 and 270 degrees.

11(Amended). An assembly [cannula] according to claim 9, wherein the angle is between 0 and 180 degrees.

REMARKS

A substitute specification is submitted herewith in marked-up form (Attachment A) as well as in clean form (Attachment B). The substitute specification amends the specification to correct typographical and clerical errors and to provide consistent reference numbers when directing to the same part. No new matter has been added.

The drawings are objected to under 37 C.F.R. §1.83(a). The Examiner states that the first and second flow paths must be shown. The specification discloses an inner cannula and an outer cannula that form a double cannula assembly (see e.g., page 13 line 28 to page 14, line 6). As illustrated in Fig. 2, the inner cannula defines a first flow path. As Fig. 2 also shows, the inner cannula is received within the interior lumen of the outer cannula. The inner and outer cannulas define between them a second flow path. The specification discloses embodiments of a double cannula assembly specifically adapted for insertion within a patient's heart (see, e.g., page 23, lines 5-8). An exemplary embodiment of such an assembly is shown in Figs. 16-19, which illustrate an outer cannula 210. To the extent that Applicants response to the Restriction Requirement mailed February 26, 2002 did not clarify that Fig. 23 represents Examiner's Species H, Applicants seek to clarify the record. In use, as illustrated in Fig. 23, an inner cannula 260 is passed within the outer cannula 210 (see also, e.g., page 28 line 21 to page 29, line 15). The interior lumen of inner cannula 260 defines a first flow path. The space between inner and outer cannulas 210 and 260 define a second flow path. As the specification discloses and illustrates first and second flow paths, Applicants respectfully request that this rejection be withdrawn.

In objecting to the drawings under 37 C.F.R. §1.83(a), the Examiner also states that the deformable flexible wire must be shown. Claims 14-16, incorporating this subject matter, have been canceled.

In objecting to the drawings under 37 C.F.R. §1.83(a), the Examiner states that the pump must be shown. Applicants note that the pump 124 is shown in Fig. 2. For clarity, Fig. 23 has been amended to also show pump 124.

The drawings are objected to under 37 C.F.R. §1.84(p)(5) because they do not include reference numbers mentioned in the description. The specification has been amended to overcome this objection as follows:

1. The specification has been amended to change reference number 300 to 310 to provide consistent reference numbers when directing to the same part (see substitute

specification, paragraph no. 66). Reference number 310 has been added to Fig. 22.

2. Reference number 241 has been added to Fig. 23.

3. Reference number 641 has been added to Fig. 24.

The drawings are objected to under 37 C.F.R. §1.84(p)(5) because they include reference signs not mentioned in the description. The specification has been amended to overcome this objection as follows:

1. Reference number 214 has been deleted from Fig. 23.

2. The specification has been amended to add reference number 611 (see substitute specification, paragraph no. 69).

3. Reference number 79 has been changed to reference number 796 in Fig. 26.

4. The specification has been amended to add reference numbers 720 and 730 (see substitute specification, paragraph no. 70).

5. The specification has been amended to add reference numbers 541, 590 and 591 (see substitute specification, paragraph no. 73).

The drawings are objected to because of minor informalities. The drawings have been amended to overcome this objection. In particular, cross-section markings have been deleted from Figs. 26 and 27.

The drawings are objected to under 37 C.F.R. §1.84(p)(4) because reference numbers 230 and 242 both designate an inflow port. As reference numbers 230 and 242 each designate a different inflow port, Applicant believes that differentiating the two inflow ports by different reference numbers is appropriate (see, e.g., Fig. 19).

The Examiner requests that the trademark NITINOL™ be capitalied and accompanied by the generic terminology. The specification has been amended accordingly.

The disclosure is objected to because of informalities. The specification has been amended to overcome these objections as follows:

1. In the brief description of the drawings, the description of Fig. 25 has been amended to state that it is a cross-section of Fig. 24.

2. In the brief description of the drawings, the description of Figs. 18 and 19 have been amended to state that they are cross-sectional and side-sectional views, respectively, of Fig. 16.

3. The substitute specification lists the claims on a separate sheet at the end of the disclosure.

Claims 2-5, 7 and 12-15 have been canceled.

Claims 1, 6 and 8-11 have been amended. In compliance with 37 C.F.R. §121(c)(3), a clean version of the entire set of pending claims is being submitted, as is a marked-up version showing changes in the amended claims relative to the previous version of the claims.

Claims 1, 6 and 8-11 remain in the application. Of these, claim 1 is an independent apparatus claim and claim .

The Examiner indicates that essential material disclosing limitations defining the combined priming volume of the pump and the first and second flow paths as set forth in claims 3-5 has been incorporated by reference. Claims 3-5 have been canceled.

Claims 1 and 3-6 are rejected under 35 U.S.C. §112, first and second paragraphs as not describing the first and second flow paths. As previously noted, the specification discloses and shows the first and second flow paths. Therefore, Applicants respectfully request that these rejections be withdrawn. Claim 3 is also rejected 35 U.S.C. §112, second paragraph because there is insufficient antecedent basis for "the pump" in line 2. Claim 3 has been canceled.

The claims are rejected in various combinations under 35 U.S.C. §102(e) as anticipated by DeVries U.S. Patent No. 6,042,576 (DeVries '576) or Aboul-Hosn U.S. Patent No. 6,083,260 (Aboul-Hosn '260) and under 35 U.S.C. §103(a) over Aboul-Hosn '260 or DeVries '576 in view of Aboul-Hosn '260. As defined by amended independent claim 1, neither of the cited references, alone or in combination, teach or suggest an inner cannula slidable within an outer cannula, wherein the outer cannula includes a curved portion that directs passage of the inner cannula beyond the distal end of the outer cannula.

Reconsideration in view of the foregoing amendments and remarks and allowance of claims 1, 6 and 8-11 is respectfully requested.

Respectfully submitted,

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